

K170005 FLEX Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 1294, Ready-to-Use (Dako Omnis)Dec 21, 2017
352 days to decisionK170005 · Product code: **MXZ** · Pathology
Source: <https://www.510kdatabase.net/k170005/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Immunohistochemistry Assay, Antibody, Progesterone Receptor (MXZ) |
| Date received | Jan 3, 2017 |
| Decision date | Dec 21, 2017 |
| Days to decision | 352 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Dako Denmark A/S |
| Location | Golstrup, DK |
| Contact | LASSE POST MOLLER |
| 510(k) history | 2 submissions · 2 cleared · 2017-2017 |

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